

John D. Thallemer
Senior Patent Attorney
Novartis Corp. Intellectual
Property

Sandoz, Inc.
506 Carnegie Center, Suite 400
Princeton NJ 08540-6243

Tel (609) 627-8507
Fax (609) 627-8636
Internet: john.thallemer
@novartis.com



Rec'd PCT/PTO 17 AUG 2006

August 16, 2006

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17 AUG 2006

Bryan Tung
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450

Legal Staff
International Division

Re: Re: BP/G-32575A/BCK, U.S. Serial # 10/520,568

Dear Mr. Tung

Thank you for your response of 02/28/06. Subsequent to filing a renewed petition under 37 CFR.1.47 (a), Michael Betz provided us with an executed declaration for submission to the UPSTO.

Therefore, we kindly request that you dismiss the above mentioned petition and accept the executed declaration.

Included along with this fax cover sheet are the following documents: Transmittal Form 2 executed declarations, Copy of USPTO response to petition filed under 37 CFR 1.47 (a),.

Very truly yours,

John Thallemer
John D. Thallemer

34,940

JDT:rd

12 Pages total.

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AUG 2006

Legal Staff
International Division

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FILING BY "FACSIMILE" UNDER 37 CFR 1.10

Fax number

8/16/2006

Date of Deposit

| | | | |
|---|---|--|---|
| Form PTO-1350-MOD (REV 10-98) | | U. S. Department of Commerce Patent and Trademark Office | ATTORNEY'S DOCKET NUMBER BP/G-32575A/BCK |
| TRANSMITTAL LETTER TO THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US) CONCERNING A FILING UNDER 35 U.S.C. 371 | | | U.S. APPLICATION NO. (if known, see 37 CFR 1.5) |
| | | | 10/520,568 |
| INTERNATIONAL APPLICATION NO. PCT/EP03/07349 | INTERNATIONAL FILING DATE 8 July 2003 (08.07.03) | PRIORITY DATE CLAIMED 9 July 2002 (09.07.02) | |
| TITLE OF INVENTION LIQUID FORMULATIONS WITH HIGH CONCENTRATION OF HUMAN GROWTH HORMONE (HGH) COMPRISING 1,2-PROPYLENE GLYCOL | | | |
| APPLICANT(S) FOR DO/EO/US BETZ ET, AL. | | | |

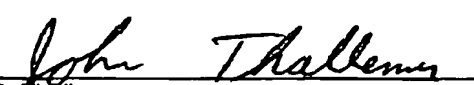
Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:

1. ☐ This is a **FIRST** submission of items concerning a filing under 35 U.S.C. 371.
2. ☒ This is a **SECOND** or **SUBSEQUENT** submission of items concerning a filing under 35 U.S.C. 371.
3. ☐ This express request to begin national examination procedures (35 U.S.C. 371(f)) at any time rather than delay examination until the expiration of the applicable time limit set in 35 U.S.C. 371(b) and PCT Articles 22 and 39(1).
4. ☐ A proper Demand for International Preliminary Examination was made by the 19th month from the earliest claimed priority date.
5. ☐ A copy of the International Application as filed (35 U.S.C. 371(c)(2))
 - a. ☐ is transmitted herewith (required only if not transmitted by the International Bureau).
 - b. ☐ has been transmitted by the International Bureau. (See Form PCT/IB/308)
 - c. ☐ is not required, as the application was filed in the United States Receiving Office (RO/US).
6. ☐ A translation of the International Application into English (35 U.S.C. 371(c)(2)).
7. ☐ Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371(c)(3)).
 - a. ☐ are transmitted herewith (required only if not transmitted by the International Bureau).
 - b. ☐ have been transmitted by the International Bureau.
 - c. ☐ have not been made; however, the time limit for making such amendments has NOT expired.
 - d. ☐ have not been made and will not be made.
8. ☐ A translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371 (c)(3)).
9. ☒ An executed Declaration and Power of Attorney (original or copy) (35 U.S.C. 371(c)(4)).
10. ☐ A translation of the annexes to the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371(c)(5)).

Items 11. to 16. below concern document(s) or information included.

11. ☐ An Information Disclosure Statement under 37 CFR 1.97 and 1.98.
12. ☐ An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included.
13. ☐ A FIRST preliminary amendment.
☐ A SECOND or SUBSEQUENT preliminary amendment.
14. ☐ An Application Data Sheet under 37 CFR 1.76.
15. ☐ A substitute specification.
16. ☐ A change of power of attorney and/or address letter.
17. ☐ A computer-readable form of the sequence listing in accordance with PCT Rule 13ter.2 and 37 CFR 1.821-1.825.
18. ☐ A second copy of the published International Application under 35 U.S.C. 154(d)(4).
19. ☐ A second copy of the English language translation of the International application under 35 U.S.C. 154(d)(4).
20. ☐ Other items or information:

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|---|---|---|----------|--|--|
| U.S. APPLICATION NO. (If known, see 37 CFR 1.5) | | INTERNATIONAL APPLICATION NO. PCT/EP03/07349 | | ATTORNEY'S DOCKET NUMBER BP/G-32575A/BCK | |
| The following fees are submitted: | | | | | CALCULATIONS <small>PTO USE ONLY</small> |
| 21. | Basic national fee. | | \$ | | |
| 22. | Examination Fee If International preliminary examination report was prepared by USPTO and all claims satisfy provisions of PCT Article 33(1)-(4) | | \$ | | |
| | All other situations. | | \$ | | |
| 23. | Search fee If Search fee (37 CFR 1.445(a)(2)) has been paid on the international application to the USPTO as an International Searching Authority. | | \$ | | |
| | If International Search Report was prepared and provided to the Office. . . | | \$ | | |
| | All other situations. | | \$ | | |
| TOTAL OF 21, 22 AND 23 = | | | | \$ | 0 |
| Additional fee for specification and drawings filed in paper over 100 sheets (excluding sequence listing or computer program listing filed in an electronic medium). The fee is \$250 for each additional 50 sheets of paper or fraction thereof. | | | | | |
| Total Sheets | Extra sheets | Number of each additional 50 or fraction thereof (round up to a whole number) | RATE | | |
| - 100 = | /50 = | | X \$ 250 | \$ | |
| Surcharge of \$130 for furnishing the oath of declaration later than <input type="checkbox"/> 30 months from the earliest claimed priority date (37 CFR 1.492(e)). | | | | \$ | |
| CLAIMS | NUMBER FILED | NUMBER EXTRA | RATE | | |
| Total claims | - 20 = | | X \$ 50 | \$ | |
| Independent claims | - 3 = | | X \$ 200 | \$ | |
| MULTIPLE DEPENDENT CLAIM(S) (if applicable) | | | + \$ 360 | \$ | |
| TOTAL OF ABOVE CALCULATIONS = | | | | \$ | 0 |
| Reduction of 1/2 for filing by small entity, if applicable. Verified Small Entity Statement must also be filed (Note 37 CFR 1.9, 1.27, 1.28). | | | | \$ | |
| SUBTOTAL = | | | | \$ | 0 |
| Processing fee of \$130 for furnishing the English translation later than <input type="checkbox"/> 30 months from the earliest claimed priority date (37 CFR 1.492(f)). | | | | + | \$ |
| TOTAL NATIONAL FEE = | | | | \$ | 0 |
| Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31). \$40 per property | | | | + | \$ |
| TOTAL FEES ENCLOSED = | | | | \$ | 0 |
| | | | | Amount to be: refunded | \$ |
| | | | | charged | \$ |
| <p>a. <input type="checkbox"/> A check in the amount of \$_____ to cover the above fees is enclosed.</p> <p>b. <input checked="" type="checkbox"/> Please charge Deposit Account No. 19-0134 in the name of Novartis in the amount of \$0 to cover the above fees. A duplicate copy of this form is enclosed.</p> <p>c. <input checked="" type="checkbox"/> The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 19-0134 in the name of Novartis.</p> <p>NOTE: Where an appropriate time limit under 37 CFR 1.494 or 1.495 has not been met, a petition to revive (37 CFR 1.137(a) or (b)) must be filed and granted to restore the application to pending status.</p> <p>Send all correspondence to the address associated with Customer No. 001095, which is currently:</p> <div style="display: flex; justify-content: space-between; margin-top: 20px;"> <div style="width: 45%;"> <p>Novartis Corporate Intellectual Property One Health Plaza, Building 104 East Hanover, NJ 07936-1080</p> </div> <div style="width: 45%; text-align: right;"> <p> John D. Thallemer Attorney for Applicant Reg. No. 34,940 (609) 627-8507</p> </div> </div> | | | | | |

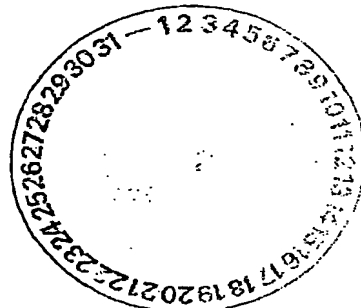
28 FEB 2006

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NOVARTIS
CORPORATE INTELLECTUAL PROPERTY
ONE HEALTH PLAZA 104/3
EAST HANOVER, NJ 07936-1080

JDT



DECISION

MAR 06 2006
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In re Application of BETZ et al
U.S. Application No.: 10/520,568
PCT Application No.: PCT/EP03/07349
Int. Filing Date: 08 July 2003
Priority Date Claimed: 09 July 2002
Attorney Docket No.: BP/G-32575A/BCK
For: LIQUID FORMULATIONS WITH HIGH
CONCENTRATION OF HUMAN GROWTH
HORMONE...

This is in response to applicant's "Renewed Petition Under 37 CFR 1.47(a)" filed 17 February 2006.

BACKGROUND

On 08 July 2003, applicant filed international application PCT/EP03/07349, which claimed priority of an earlier United States application filed 09 July 2002. A copy of the international application was communicated to the USPTO from the International Bureau on 15 January 2004. The thirty-month period for paying the basic national fee in the United States expired on 09 January 2005.

On 07 January 2005, applicant filed national stage papers in the United States Designated/Elected Office (DO/EO/US). The submission was accompanied by, *inter alia*, the basic national fee required by 35 U.S.C. 371(c)(1).

On 25 July 2005, the DO/EO/US mailed a Notification of Missing Requirements Under 35 U.S.C. 371 (Form PCT/DO/EO/905), which indicated that an oath or declaration in compliance with 37 CFR 1.497 must be filed.

On 16 December 2005, applicant filed a petition under 37 CFR 1.47(a).

DOCKETED FOR: Aug 28, 2006

ansp dead: Aug 28 2006

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Application Number: 10/328,568

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On 24 January 2006, this Office mailed a decision dismissing the 16 December 2005 petition.

On 17 February 2006, applicant filed the present renewed petition under 37 CFR 1.47(a).

DISCUSSION

A petition under 37 CFR 1.47(a) must be accompanied by: (1) an oath or declaration by each applicant on his or her own behalf and on behalf of the nonsigning joint inventors, (2) factual proof that the missing joint inventors refuse to join in the application or cannot be reached after diligent effort, (3) the fee set forth in §1.17(i), and (4) the last known addresses of the nonsigning joint inventors.

Applicant has previously satisfied items (1), (3), and (4) above.

With regard to item (2) above, MPEP 409.03(d) states in relevant part,

Where a refusal to sign the application papers is alleged, the circumstances of this refusal must be specified in an affidavit or declaration by the person to whom the refusal was made. Statements by a party not present when an oral refusal is made will not be accepted.

Before a refusal can be alleged, it must be demonstrated that a bona fide attempt was made to present a copy of the application papers (specification, including claims, drawings, and oath or declaration) to the nonsigning inventor for signature. A copy of the application papers should be sent to the last known address of the nonsigning inventor, or, if the nonsigning inventor is represented by counsel, to the address of the nonsigning inventor's attorney.

When there is an express oral refusal, that fact along with the time and place of the refusal must be stated in the affidavit or declaration. When there is an express written refusal, a copy of the document evidencing that refusal must be made part of the affidavit or declaration.

When it is concluded by the 37 CFR 1.47 applicant that a nonsigning inventor's conduct constitutes a refusal, all facts upon which that conclusion is based should be stated in the affidavit or declaration. If there is documentary evidence to support facts alleged in the affidavit or declaration, such evidence should be submitted. Whenever a nonsigning inventor gives a reason for refusing to sign the application oath or declaration, that reason should be stated in the affidavit or declaration.

⇒ The petition states that joint inventor Michael Betz refuses to sign the application papers. However, the petition does not adequately demonstrate that a bona fide attempt was made to present a complete copy of the application papers (including specification, claims, drawings, and oath/declaration) to Betz for signature. Although the petition states that Betz was provided with a copy of the present application, the reply letter from Betz mentions only declaration and assignment forms. As stated in the decision mailed 24 January 2006, a copy and translation of the original letter to Betz (i.e. the letter to which Betz responded to on 17 December 2004) has not been provided. If a copy of such letter cannot be obtained, then applicant should submit an affidavit from the person who sent the letter to Betz. Because it cannot be determined from the

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*Application Number: 10/520,568

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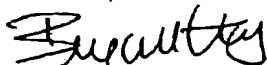
presented evidence that Betz received all of the application papers, it would not be reasonable to conclude at the present time that Betz refuses to join in the application.

CONCLUSION

For the reasons above, the petition under 37 CFR 1.47(a) is DISMISSED without prejudice.

If reconsideration on the merits of this petition is desired, a proper response must be filed within TWO (2) MONTHS from the mail date of this decision. Extensions of time are available under 37 CFR 1.136(a). Any reconsideration request should include a cover letter entitled "Renewed Petition Under 37 CFR 1.47(a)". No additional petition fee is required.

Please direct further correspondence with respect to this matter to Mail Stop PCT, Commissioner for Patents, Office of PCT Legal Administration, P.O. Box 1450, Alexandria, Virginia 22313-1450, with the contents of the letter marked to the attention of the Office of PCT Legal Administration.



Bryan Tung
PCT Legal Examiner
PCT Legal Office

Telephone: 571-272-3303
Facsimile: 571-273-0459

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